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**SUBSTITUTE SENATE BILL 6302**

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**State of Washington**

**60th Legislature**

**2008 Regular Session**

**By** Senate Health & Long-Term Care (originally sponsored by Senators Kohl-Welles, Keiser, Fairley, Kline, Franklin, and Regala)

READ FIRST TIME 01/25/08.

1       AN ACT Relating to reporting of gifts, fees, or payments by  
2 pharmaceutical marketers; adding a new chapter to Title 69 RCW; and  
3 prescribing penalties.

4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

5       NEW SECTION. **Sec. 1.** The purpose of this chapter is to regulate  
6 gifts, grants, and gratuities made by pharmaceutical manufacturing  
7 companies, directly or indirectly, to any person or entity authorized  
8 to prescribe, dispense, or purchase prescription drugs in Washington.

9       NEW SECTION. **Sec. 2.** The legislature finds that:

10       (1) The state of Washington has an interest in maximizing the well-  
11 being of its residents and containing health care costs;

12       (2) There is a strong link between pharmaceutical marketing  
13 activities, health care spending, and the health of Washingtonians;

14       (3) In 2004, the pharmaceutical industry spent twenty-seven billion  
15 dollars marketing pharmaceuticals in the United States. Over eighty-  
16 five percent of these marketing expenditures are directed at the small  
17 percentage of the population that practice medicine. Pharmaceutical

1 manufacturers spend twice as much on marketing as on research and  
2 development;

3 (4) Marketing programs are designed to increase sales, income, and  
4 profit. Frequently, progress toward these goals comes at the expense  
5 of evidence-based treatment and sometimes the health of individual  
6 patients;

7 (5) There is considerable evidence that pharmaceutical marketing  
8 campaigns lead doctors to prescribe drugs based on incomplete and  
9 biased information, particularly for prescribers who lack the time to  
10 perform substantive research assessing whether the messages they are  
11 receiving from pharmaceutical representatives are full and accurate;

12 (6) A significant portion of prescriber time is spent meeting with  
13 pharmaceutical representatives. According to a survey published in the  
14 New England Journal of Medicine, family practitioners reported the  
15 highest frequency of meetings with representatives, an average of  
16 sixteen times per month. To the extent that this meeting time comes at  
17 the expense of time spent with patients, quality of care is negatively  
18 affected;

19 (7) The federal food and drug administration requires marketing and  
20 advertising to be fair and balanced; however, the federal food and drug  
21 administration has limited legal ability to enforce this requirement;

22 (8) Newer drugs on the market do not necessarily provide evidence-  
23 based benefits over older drugs but do add costs and as yet unknown  
24 side effects;

25 (9) Between 1975 and 2000, fifty percent of all drug withdrawals  
26 from the market and "black box warnings" were within the first two  
27 years of the release of the drug. One-fifth of all drugs are subject  
28 to "black box warnings" or withdrawal from the market because of  
29 serious public health concerns. Marketing that results in prescribers  
30 using the newest drugs also results in prescribing drugs that are more  
31 likely to be subject to these warnings and withdrawal;

32 (10) Nearly one-third of the five-fold increase in spending in the  
33 United States on drugs over the last decade can be attributed to  
34 marketing-induced shifts in doctors' prescribing from existing,  
35 effective, and lower cost, often generic, therapies to new and more  
36 expensive treatments, which often have little or no evidence-based  
37 therapeutic value;

1 (11) Several studies suggest that drug samples clearly affect  
2 prescribing behavior in favor of the sample, and that the presence of  
3 drug samples may influence physicians to dispense or prescribe drugs  
4 that differ from their preferred drug source;

5 (12) The pharmaceutical industry increased its spending on direct  
6 marketing to doctors by over two hundred seventy-five percent and  
7 doubled its sales force to over ninety thousand drug representatives.  
8 It is estimated that there is a pharmaceutical sales representative for  
9 every five office-based physicians.

10 NEW SECTION. **Sec. 3.** The definitions in this section apply  
11 throughout this chapter unless the context clearly requires otherwise.

12 (1) "Board" means the board of pharmacy.

13 (2)(a) "Gift, fee, or payment" includes any subsidy or other  
14 economic benefit provided in connection with detailing, promotional, or  
15 other marketing activities by the company directly or through any other  
16 entity at the direction of or with the implied or express knowledge of  
17 the company, including:

18 (i) Food or entertainment;

19 (ii) Trips or travel;

20 (iii) Anything provided for less than market value;

21 (iv) Medical conferences, continuing medical education, or other  
22 educational or informational programs, materials, and seminars, and  
23 remuneration for promoting or participating in educational or  
24 informational sessions;

25 (v) Consulting fees or honoraria;

26 (vi) Product samples, including samples that will be distributed  
27 free of charge to patients; and

28 (vii) Clinical trials or research, including any compensation or  
29 reimbursement of expenses.

30 (b) "Gift, fee, or payment" does not include:

31 (i) Payments made in conjunction with returned merchandise and  
32 overpayments;

33 (ii) Publications and educational materials;

34 (iii) Salaries or other benefits paid to its employees;

35 (iv) Overpayments;

36 (v) Product rebates and discounts; and

1 (vi) Other normal course-of-business financial dealings unrelated  
2 to detailing, promotional, or other marketing activities.

3 (3) "Group purchasing organization" means any group of two or more  
4 hospitals, nursing homes, or other health care organizations that  
5 collectively purchase either directly from a pharmaceutical  
6 manufacturing company or by accessing contracts through another group.

7 (4) "Health benefit plan administrator" means any person or entity  
8 who manages or administers a private, self-insured health benefit plan  
9 or public employee health benefit plan and any person who manages or  
10 administers health benefit plans for another person, including health  
11 insuring corporations and sickness and accident insurers under contract  
12 to provide managerial and administrative services.

13 (5)(a) "Marketing" means any of the following activities undertaken  
14 or materials or products made available to prescribers or to their  
15 employees or agents related to the transfer of prescription drugs from  
16 the producer or seller to the consumer or buyer:

17 (i) Advertising, publicizing, promoting, or selling a prescription  
18 drug;

19 (ii) Activities undertaken for the purpose of influencing the  
20 market share of a prescription drug or the prescribing patterns of a  
21 prescriber, a detailing visit, or a personal appearance;

22 (iii) Activities undertaken to evaluate or improve the  
23 effectiveness of a professional detailing sales force; or

24 (iv) A brochure, media advertisement or announcement, poster, or  
25 free sample of a prescription drug.

26 (b) "Marketing" does not include pharmacy reimbursement, formulary  
27 compliance, pharmacy file transfers in response to a patient request or  
28 as a result of the sale or purchase of a pharmacy, patient care  
29 management, utilization review by a health care provider or agent of a  
30 health care provider or the patient's health plan or an agent of the  
31 patient's health plan, and health care research.

32 (6) "Pharmaceutical detailing, promotional, or marketing  
33 activities" means promotional or educational activities by  
34 pharmaceutical marketers directed at physicians, their staff, or other  
35 health care professionals who prescribe, dispense, or administer  
36 prescription drugs.

37 (7)(a) "Pharmaceutical manufacturer" means an entity that is  
38 engaged in the production, preparation, propagation, compounding,

1 conversion, or processing of prescription drugs, either directly or  
2 indirectly by extraction from substances of natural origin, or  
3 independently by means of chemical synthesis, or by a combination of  
4 extraction and chemical synthesis, or any entity engaged in the  
5 packaging, repackaging, labeling, relabeling, or distribution of  
6 prescription drugs.

7 (b) "Pharmaceutical manufacturer" does not include pharmacists or  
8 pharmacies licensed under chapter 18.64 RCW or pharmacy operations of  
9 any integrated delivery system undertaken for the benefit of patients  
10 obtaining care through that system.

11 (8) "Pharmaceutical marketer" means a person, agent, or  
12 representative who, while employed by or under contract to represent a  
13 pharmaceutical manufacturing company, engages in pharmaceutical  
14 detailing, promotional activities, or other marketing of prescription  
15 drugs in this state to any entity or person authorized to prescribe,  
16 dispense, or purchase prescription drugs in this state.

17 (9) "Pharmacy benefit manager" means a person or business entity  
18 that administers or otherwise assists with prescription drug benefit  
19 services including formulary management, rebates, discounted pharmacy  
20 network, mail service pharmacies, and electronic claims processing.  
21 Such services may be provided on behalf of a health insurer, an  
22 employer-sponsored health benefit plan, or an agency of the state.

23 (10) "Recipient" means any:

24 (a) Health care professional licensed under Title 18 RCW who is  
25 authorized to prescribe or dispense prescription drugs or entity that  
26 employs such a professional;

27 (b) Hospital licensed under chapter 70.41 RCW;

28 (c) Health benefit plan administrator;

29 (d) Group purchasing organization or pharmacy benefit manager; or

30 (e) Other entity authorized to purchase prescription drugs in this  
31 state.

32 NEW SECTION. **Sec. 4.** Starting January 1, 2009, and annually  
33 thereafter, every pharmaceutical manufacturer shall:

34 (1) Disclose to the board information on each gift, fee, or payment  
35 made to recipients in the state;

36 (2) Submit information in a form and manner determined by the  
37 board, including for each expenditure:

- 1 (a) The value and nature;
- 2 (b) The purpose according to categories specified by the board; and
- 3 (c) The recipient, including the recipient's address, credentials,
- 4 and institutional affiliation;
- 5 (3) Disclose to the board the name and address of the individual
- 6 responsible for the company's compliance with the provisions of this
- 7 section or, if this information has been previously reported, any
- 8 changes to the name or address of the individual responsible for the
- 9 company's compliance with the provisions of this section;
- 10 (4) Pay a fee, to be set by the board, to support the work of the
- 11 board under this chapter.

12 NEW SECTION. **Sec. 5.** The board shall:

- 13 (1) Report annually on disclosures made under this chapter to the
- 14 legislature and the governor on or before March 1st of each year;
- 15 (2) Post specific and easily searchable data on its public internet
- 16 site, including:
- 17 (a) Amount of each gift;
- 18 (b) Date given;
- 19 (c) Intended purpose of the gift;
- 20 (d) Pharmaceutical manufacturer; and
- 21 (e) Recipient identified by drug enforcement agency number or other
- 22 unique identifier.

23 NEW SECTION. **Sec. 6.** The attorney general may bring an action in

24 Thurston county superior court for injunctive relief, costs, and

25 attorneys' fees, and to impose on a pharmaceutical manufacturing

26 company that fails to comply with this chapter a civil penalty of not

27 more than ten thousand dollars per violation. Each unlawful failure to

28 disclose constitutes a separate violation.

29 NEW SECTION. **Sec. 7.** The board may adopt rules to implement the

30 provisions of this chapter.

31 NEW SECTION. **Sec. 8.** This chapter may be known and cited as the

32 prescription drug marketing and disclosure act.

1        NEW SECTION.   **Sec. 9.**  If any provision of this act or its  
2 application to any person or circumstance is held invalid, the  
3 remainder of the act or the application of the provision to other  
4 persons or circumstances is not affected.

5        NEW SECTION.   **Sec. 10.**  Sections 1 through 9 of this act constitute  
6 a new chapter in Title 69 RCW.

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